REMARKS

This application is the national phase filing of PCT application PCT/EP00/02917. The claims have been amended to eliminate multiple dependencies, provide antecedent basis for terms in dependent claims, and to conform to U.S. practice. The scope of the claims is believed unchanged.

No new matter has been added and entry of the amendment is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 246152015300. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

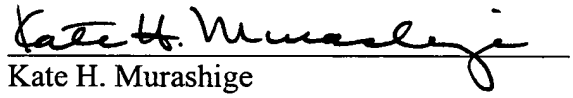
Dated: September 28, 2001 By: 

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EXHIBIT A. - VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. Agglomerates in crystalline form comprising one or more β-lactam compounds, wherein at least one β-lactam compound has a high water affinity, and optionally containing one or more excipients, with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded.

2. Agglomerates according to claim 1, wherein the agglomerates are substantially free from non-agglomerated β-lactam crystals.

3. (Amended) Agglomerates according to claim 1[or 2], wherein at least one β-lactam compound is clavulanic acid.

4. (Amended) Agglomerates according to [any one of the claims 1-3] claim 1, wherein the β-lactam compound is potassium clavulanate.

5. Agglomerates according to claim 4, consisting of only potassium clavulanate.

6. Agglomerates according to claim 4 further comprising amoxicillin.

7. (Amended) Agglomerates according to [anyone of the claims 1-4 or 6] claim 1, wherein the one or more excipients are selected from the group consisting of microcrystalline cellulose[, preferably Avicel®, or] and silica[, preferably Syloid® or Aerosil®].

8. (Amended) Agglomerates according to [anyone of the claims 1-7] claim 1, wherein the agglomerates have an average particle size between about 1 μm and 1500 μm[, preferably between about 500 μm and 1500 μm, more preferably between 800 μm and 1200 μm, or preferably between 1 μm and 300 μm, more preferably between 1 μm and 200 μm].

9. (Amended) Agglomerates according to [anyone of the claims 1-8] claim 1 in sterile form.

10. (Amended) A process for the [preparation of] preparing the crystallised agglomerates [as defined in anyone of the claims 1-9] of claim 1, [wherein the agglomerates are produced in a liquid phase by applying] which comprises stirring at least one β-lactam in a liquid phase [devices].

11. (Amended) A process according to claim 10, wherein the liquid phase [comprises a solution or suspension of at least one corresponding β-lactam compound in] comprises a solvent or in a mixture of solvents together with one or more anti-solvents.

12. (Amended) A process according to claim 11, wherein the ratio of the weight of the [solution] solvent containing β-lactam [compound] to the anti-solvent is about 0.05 to 10 wt.%.

13. (Amended) A process according to claim 11[or 12], wherein the solvent is selected from the group consisting of water, an alcohol, a ketone and an ester [or a] and mixtures thereof, [whereby] wherein water is present in said mixture.

14. (Amended) A process according to [anyone of the claims 10-13] claim 10, wherein the anti-solvent is a ketone, [like acetone, methylethylketone, methylisobutylketone or] an ester, [like methyl acetate, ethyl acetate, isopropyl acetate, butyl acetate] or an alcohol, [like 1-propanol, 1-butanol, 2-butanol, 2-methyl-1-propanol] or a mixture of these anti-solvents, optionally containing water.

16. (Amended) A process according to claim [15] 10, wherein the [process] stirring is performed by applying stirring devices in one or more vessels, in-line mixers or a combination thereof.

17. (Amended) A process according to claim [15 or] 16, wherein [a high shear mixer is used as] the stirring device is a high shear mixer.

18. (Amended) A process according to [anyone of the claims 10-17] claim 25, [characterised by the preparation of agglomerates with various particle sizes, by further using a] wherein said stirring is performed by combining and permuting [combination and permutation of] different stirring devices, [and their] the speeds of said devices, the type and amount of the solvents used, and [the way of] mixing [of] one or more solvents and anti-solvents.

19. (Amended) A process according to claim 18, [characterised by the preparation of] wherein the agglomerates [with] have various particle sizes[, by further using a nozzle-sprayer for the solution].

20. (Amended) A process according to [any one of the claims 10-19] claim 11, [characterised by] wherein the process comprises dissolving one or more [corresponding] β-lactams in a solvent, adjusting the pH to about neutral and mixing with the anti-solvent.

21. (Amended) A pharmaceutical formulation comprising the agglomerates of [anyone of the claims 1-9] claim 1 and one or more pharmaceutically acceptable excipients.

22. (Amended) A pharmaceutical formulation comprising [amoxicillin, preferably amoxicillin trihydrate and] the crystalline agglomerates of potassium clavulanate [as defined in] of claim 5, amoxicillin and optionally one or more pharmaceutically acceptable inert excipients.

23. (Amended) [A] The pharmaceutical formulation[, comprising a mixture of amoxicillin trihydrate and crystalline agglomerates of potassium clavulanate and one or more] of claim 22 which contains one or more pharmaceutically acceptable inert excipients [as defined in claim 4] selected from the group consisting of microcrystalline cellulose and silica.

24. (Amended) [Pharmaceutical] A pharmaceutical dosage form comprising a pharmaceutical formulation of [anyone of the claims 21-23] claim 21.